

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

VANDA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	REDACTED - PUBLIC VERSION
v.	)	C.A. No. 18-651-CFC
	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Defendant.	)	
	)	
VANDA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	REDACTED - PUBLIC VERSION
	)	C.A. No. 18-689-CFC
v.	)	
	)	
APOTEX INC. and APOTEX CORP.,	)	
	)	
Defendants.	)	
	)	
VANDA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	REDACTED - PUBLIC VERSION
	)	C.A. No. 18-690-CFC
v.	)	
	)	
MSN PHARMACEUTICALS INC. and	)	
MSN LABORATORIES PRIVATE	)	
LIMITED,	)	
	)	
Defendants.	)	
	)	

**LETTER TO THE HONORABLE COLM F. CONNOLLY FROM K. KELLER**

OF COUNSEL:

J.C. Rozendaal  
Deirdre M. Wells  
William H. Milliken  
STERNE, KESSLER, GOLDSTEIN  
& FOX P.L.L.C.  
1100 New York Avenue, N.W.  
Suite 600  
Washington, DC 20005  
(202) 772-8747

Dated: February 4, 2019

John W. Shaw (No. 3362)  
Karen E. Keller (No. 4489)  
Nathan R. Hoeschen (No. 6232)  
SHAW KELLER LLP  
I.M. Pei Building  
1105 North Market Street, 12th Floor  
Wilmington, DE 19801  
(302) 298-0700  
jshaw@shawkeller.com  
kkeller@shawkeller.com  
nhoeschen@shawkeller.com  
*Attorneys for Defendant Teva  
Pharmaceuticals USA, Inc.*

# SHAW KELLER LLP

Karen E. Keller  
I.M. Pei Building  
1105 North Market Street, 12<sup>th</sup> Floor  
Wilmington, DE 19801  
(302) 298-0702 - Direct  
kkeller@shawkeller.com

February 4, 2019

**VIA CM/ECF & HAND DELIVERY**

The Honorable Colm F. Connolly  
U.S. District Court for the District of Delaware  
844 North King Street  
Wilmington, DE 19801

[REDACTED]  
REDACTED - PUBLIC VERSION

Re: *Vanda Pharmaceuticals Inc. v. Teva Pharmaceuticals Inc.* (C.A. No. 18-651-CFC),  
*Apotex Inc. and Apotex Corp.* (C.A. No. 18-689-CFC), and *MSN Pharmaceuticals Inc. and*  
*MSN Laboratories Private Limited* (C.A. No. 18-690-CFC)

Dear Judge Connolly:

This firm, together with Sterne, Kessler, Goldstein & Fox, represents Defendant Teva Pharmaceuticals Inc. We write on behalf of all Defendants in the above cases to seek the Court's assistance in resolving a protective order dispute with Plaintiff Vanda Pharmaceuticals Inc. Pursuant to the Scheduling Order (D.I. 30 ¶ 5), Defendants submit this letter and respectfully request that the Court enter the Proposed Protective Order attached as Exhibit 2 in its entirety.

The parties agree on the majority of the Proposed Protective Order, including the FDA bar in Paragraph 11. The sole dispute relates to Defendants' requested exemption for in-house counsel to continue working to obtain approval of or to amend a party's *own* Abbreviated New Drug Application ("ANDA") or New Drug Application ("NDA"). There is no injury risk if in-house counsel works to obtain approval of or amend its own ANDA or NDA. But if prevented from such work, Defendants would be severely prejudiced.

## **I. Background**

This is a Hatch-Waxman Act patent case. Defendants filed ANDAs with the FDA seeking approval for generic versions of the Hetlioz® (tasimelteon) drug product. Vanda holds the Hetlioz® NDA. Defendants have produced thousands of pages of their ANDAs and expect to produce more information regarding their products, including correspondence with the FDA.

The parties' discussions regarding the protective order focused primarily on the scopes of the patent prosecution bar (which generally bars protective-order subscribers from participating in tasimelteon-related patent prosecution) and the FDA bar (which generally bars protective-order subscribers from participating in tasimelteon-related FDA correspondence). *See* Ex. 2 ¶¶ 10-11. The parties generally agreed that both bars were appropriate. However, Vanda requested an exemption to the prosecution bar, and Defendants requested an exemption to the FDA bar.

For its part, Vanda requested that "each defendant's proposed label, prescribing information, medication guides, and financial projections, forecasts, and market analysis" be exempted from the prosecution bar. *See* Ex. 2 ¶ 1(c). Vanda explained that [REDACTED] a prosecution bar without Vanda's proposed exemption would be extremely

The Honorable Colm F. Connolly  
Page 2

burdensome. Although the resulting two-tier confidentiality system costs Defendants additional time and expense, in an effort to accommodate Vanda's unique situation and to reach agreement, Defendants consented to Vanda's prosecution bar exemption.

Defendants similarly requested that Vanda agree to an exemption to the FDA bar to allow in-house counsel to work to obtain approval of or amend a party's own ANDA or NDA. Defendants specifically requested the inclusion of the clarifying sentence underlined below.

In addition, any person who receives "Highly Confidential – Prosecution Bar" information . . . shall not participate in the preparation or submission of any FDA correspondence (including, but not limited to citizens petitions) or correspondence with the United States Pharmacopoeia, or any other similar foreign or domestic agency regarding approval requirements of tasimelteon formulations. . . . For clarity, this restriction does not include Plaintiff's and Defendants' work to obtain approval of, or amending, their respective NDA and ANDAs.

Ex. 2 ¶ 11 (emphasis added). This exemption allows in-house counsel to ensure that representations and submissions in this litigation and to the FDA are consistent and accurate.

Despite Defendants' compromise on Vanda's prosecution bar exemption, Vanda rejected Defendants' proposal. Vanda insisted on either deleting the underlined sentence or removing the FDA bar altogether; it would not agree to include an FDA bar with the proposed exemption.

## II. Legal Standard

Once good cause is shown to include an FDA bar, the question then becomes whether Defendants' proposed exemption poses an unacceptable risk of inadvertent disclosure. *See In re Deutsche Bank Trust Co. Ams.*, 605 F.3d 1373, 1378 (Fed. Cir. 2010). But "[e]ven if a district court is satisfied that such a risk exists, the district court must balance this risk against the potential harm to [Defendants] from restrictions imposed on [their] right to have the benefit of counsel of its choice." *Id.* at 1380. "[E]ach case should be decided based on the specific facts involved therein." *Id.* at 1379.

## III. Argument

Defendants' FDA bar properly balances the risk of inadvertent disclosure, which has the potential to delay approval of Defendants' products, with the practical realities of this case. The risk of delaying FDA approval of generic tasimelteon from inadvertent disclosure of Defendants' information is unacceptable. The proposed exemption is equally necessary so in-house counsel can ensure the representations before both this Court and the FDA are consistent and accurate. There is no risk to Vanda. Nothing Defendants learn from Vanda's information risks giving Defendants an unfair advantage in continuing working on their *own* ANDAs.

### a. An FDA bar—which Vanda does not oppose—is necessary to prevent risk of inadvertent disclosure and delay of generic tasimelteon products

An FDA bar is necessary to lessen the risk of inadvertent disclosure of confidential

The Honorable Colm F. Connolly  
Page 3

information. “Courts have recognized...that there may be circumstances in which even the most rigorous efforts of the recipient of such information to preserve confidentiality in compliance with the provisions of . . . a protective order may not prevent inadvertent compromise.” *In re Deutsche Bank*, 605 F.3d at 1378. Here, Vanda agrees to (or at least does not oppose) a FDA bar.

FDA correspondence sent after viewing Defendants’ confidential information presents a significant risk. Once Defendants’ confidential information is seen, it cannot be unseen. “[I]t is very difficult for the human mind to compartmentalize and selectively suppress information once learned, no matter how well-intentioned.” *Id.* (citation omitted). As one example, Citizen Petitions allow a party such as Vanda to petition the FDA to add or alter a product’s indication or to request information from ANDA applicants, which can delay approval of generic products.<sup>1</sup> This unacceptable risk is not abstract or hypothetical: at least one tasimelteon Citizen Petition has already been filed.<sup>2</sup> Vanda may submit responses to the FDA regarding the prior Citizen Petition or may submit additional Citizen Petitions. An FDA bar is warranted.

**b. The proposed exemption—which is necessary to ensure accuracy and consistency across venues—poses no risk of injury**

[REDACTED] Tellingly, this exemption is typical in pharmaceutical cases. *See, e.g., Genentech, Inc. and City of Hope v. Samsung Bioepis, Ltd.*, C.A. No. 18-1363-CFC, D. Del., D.I. 38 at ¶ 33(b)(ii) (protective order that prevents disclosure of confidential information to persons involved in “the preparation of regulatory submissions to the FDA relating to [the active ingredient at issue in the case], . . . except where such FDA activities . . . relate solely to preparation of submissions in connection with obtaining or maintaining the Receiving Party’s own regulatory approval”); *IBSA Institute Biochimique, S.A., Altergon, S.A., Mist Acquisition, LLC and Mist Pharmaceuticals, LLC v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 18-555-LPS, D. Del., D.I. 25 at § 23 (FDA bar “restriction does not include Plaintiffs’ and Defendant’s work to obtain approval of, or amending, their respective NDA and ANDA”); *Vivus, Inc. v. Actavis Labs. FL, Inc.*, No. 14-cv-3786, 2016 WL 590212, at \*3 (D.N.J. Feb. 11, 2016) (FDA bar excludes “correspondence or activities . . . relating to obtaining or maintaining approval for a party’s own NDA [or] ANDA”).

The exemption presents no injury risk to Vanda, and Vanda has identified none. Rather, Vanda’s willingness to agree to a protective order *without* an FDA bar suggests that it is not concerned about the risk of injury as a result of FDA correspondence. Vanda’s positions are contradictory: Vanda’s willingness to have a strict FDA bar shows the FDA bar is unobjectionable, and Vanda’s willingness to have no FDA bar shows the proposed exemption is unobjectionable. Defendants’ middle-ground proposal strikes a balance between the competing interests at stake—weighing the risks of inadvertent disclosure versus the practical needs of the parties’ in-house counsel to perform their job responsibilities.

<sup>1</sup> *See, e.g.,* <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM622235.pdf>

<sup>2</sup> <https://www.citizen.org/sites/default/files/2265.pdf>

The Honorable Colm F. Connolly  
Page 4

Respectfully submitted,

*/s/ Karen E. Keller*

Karen E. Keller (No. 4489)

cc: All counsel of record (by CM/ECF & e-mail)  
Clerk of Court (by hand delivery)

# Exhibit 1

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

VANDA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 18-651-CFC
	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Defendant.	)	
	)	
VANDA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 18-689-CFC
	)	
APOTEX INC. and APOTEX CORP.,	)	
	)	
Defendants.	)	
	)	
VANDA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 18-690-CFC
	)	
MSN PHARMACEUTICALS INC. and	)	
MSN LABORATORIES PRIVATE	)	
LIMITED,	)	
	)	
Defendants.	)	
	)	

**DECLARATION OF KAREN E. KELLER**



I, Karen E. Keller, declare as follows:

1. I am counsel of record for Teva Pharmaceuticals USA, Inc. (“Teva”).
2. Pursuant to the Court’s procedures, the parties made a reasonable effort to resolve the dispute but were unable to reach agreement.
3. The reasonable effort to resolve this dispute included oral communications that involved Delaware counsel.

I declare under penalty of perjury of law that the foregoing is true and correct.

Date: February 4, 2019

Respectfully submitted,

/s/ Karen E. Keller

Karen E. Keller (No. 4489)

# **Exhibit 2**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

VANDA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 18-651 (CFC) (CJB)
	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Defendant.	)	

VANDA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 18-689 (CFC) (CJB)
	)	
APOTEX INC. and APOTEX CORP.,	)	
	)	
Defendants.	)	

VANDA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 18-690 (CFC) (CJB)
	)	
MSN PHARMACEUTICALS INC. AND	)	
MSN LABORATORIES PRIVATE	)	
LIMITED,	)	
	)	
Defendants.	)	

**[PROPOSED] STIPULATED PROTECTIVE ORDER**

Pursuant to Federal Rule of Civil Procedure 26(c), the parties hereby stipulate that:

1. Any document or thing or portion thereof produced by a party to the above-captioned cases or a non-party producing information pursuant to Fed. R. Civ. P. 45 (“producing party”) may be designated by the producing party as “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar.”

a) A party may designate as “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” material which that party in good faith believes comprises, discloses, or relates to confidential and proprietary business information, processes, operations, research, technical or developmental information, production, marketing, sales, shipments or other proprietary data or confidential information of commercial value, including, but not limited to, trade secrets, or information subject to confidentiality obligations to third parties, which information is not publicly known.

b) Each such document or portion thereof, or thing, shall be clearly marked or stamped with the legend “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” or “HIGHLY CONFIDENTIAL – PROSECUTION BAR.” Such legend shall be placed on every page of a multi-page document. Such legend need not be placed on the original document of the producing party, but may instead be placed upon copies produced or exchanged. All “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” information not reduced to documentary or tangible form or which cannot be conveniently designated in the manner set forth above, such as models or electronic files in native format, shall be designated by informing the receiving party in writing, and/or by so labeling the media on which the information is produced.

c) The parties acknowledge and agree that to the extent it is produced, the following information concerning the products accused in this case as they apply to method-of-use patents shall not be designated as “Highly Confidential – Prosecution Bar”: each defendant’s proposed label, prescribing information, medication guides, and financial projections, forecasts, and market analysis.

2. Interrogatories or answers thereto, requests for admissions or responses thereto, motions, briefs, memoranda, correspondence and other documents (or portions of the foregoing) prepared, produced, and served and/or filed in connection with the above-captioned cases containing “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” information, or quoting or referring to the substance of “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” information, shall be designated as “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” in accordance with Paragraph 1.

3. All information disclosed orally (such as by deposition) may similarly be designated by any party as “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar.” All transcripts of deposition or hearing testimony shall be treated as “Highly Confidential – Prosecution Bar” in their entirety until thirty (30) days following the date of the deposition or hearing. Thereafter, the information contained in the transcript will no longer be deemed “Highly Confidential – Prosecution Bar” unless: (1) within thirty (30) days of the date of the deposition or hearing, the party designating such transcript as “Highly Confidential – Prosecution Bar” or “Highly Confidential – Attorneys’ Eyes Only” provides to the other parties written notice that identifies the portions of the transcript that contain “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” information; or (2) at the deposition or hearing, counsel for the producing party states on the record that certain portions or the entirety of the transcript contains “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” information.

4. In the event a producing party elects to produce “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” information for inspection,

no marking need be made by the producing party in advance of inspection, and all information produced for inspection shall be treated as “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” during inspection. Thereafter, upon selection of specified material for copying by the inspecting party, copies of such documents that contain “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” information shall be marked with the appropriate confidentiality marking. “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” information inspected, but not selected for copying, by the inspecting party shall thereafter be treated as “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar.” If the producing party discovers after inspection is complete that it has inadvertently produced “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” information that has not been properly designated as such, the producing party may correct that error by identifying to the receiving party in writing the “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” information. The parties agree thereafter to treat that information in accordance with this Order.

5. Information which becomes available to any party via inspection, measuring, analyzing, or testing of any sample or thing designated as “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” pursuant to Paragraph 1, or which is prepared or derived by utilizing information designated as “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” and supplied under this Order, shall also be considered “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” information under this Order.

6. Regarding information designated “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” as described in this Order, (subject to the exceptions contained in Paragraphs 17 and 18 below), the receiving party shall not disclose such information to others unless by specific order of this Court or by written consent of the producing party, and shall use such information only for the purpose of the prosecution and/or defense of the above-captioned cases, and for no other purpose—including, without limitation, for purposes of preparing, filing, or prosecuting any patent application, continuation, or divisional patent application, reissue patent application, or request for reexamination.

7. Information designated “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” as described in this Order shall be deemed and treated as “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” information unless and until the Court rules to the contrary or the parties agree that the designation will be removed. Any access to “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” information or use or disclosure thereof shall be limited, unless and until the Court rules that there may be further disclosure, to the following:

a) Attorneys employed by law firms of record for the parties in the above-captioned cases, and secretarial, clerical and paralegal, and other supporting personnel who are assisting those attorneys in the above-captioned cases, and contract or temporary attorneys retained by law firms of record for the parties in the case, provided such contract or temporary attorneys acknowledge that they will abide by this Order by signing the attached acknowledgment;

b) Court reporters and videographers taking testimony involving information designated as “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” and necessary stenographic and clerical personnel thereof;

c) Litigation support consultants engaged to provide services relating to document processing, indexing, scanning, imaging, or storage, translation, demonstrative exhibits, graphics, charts, animations, design services and/or non-technical jury services, provided they acknowledge that they will abide by this Order by signing the attached Acknowledgement. Where a company or firm is retained for such litigation support, it shall be sufficient for purposes of this Order that a representative of such company or firm sign the attached Acknowledgement on behalf of the company or firm. Such representative shall be responsible for ensuring that any employee, consultant, or representative of that company or firm who receives “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” information abides by the provisions of this Order;

d) Consultants or experts and their staffs to the extent cleared by the parties pursuant to Paragraph 9 of this Order, provided the consultants or experts acknowledge that they and their staffs will abide by this Order by signing the attached Acknowledgement. Where a company or firm is retained as a consultant or expert, it shall be sufficient for purposes of this Order that a representative of such company or firm sign the attached Acknowledgement on behalf of the company or firm. Such representative shall be responsible for ensuring that any employee, consultant, or representative of that company or firm who receives “Highly Confidential – Attorneys’



Eyes Only” or “Highly Confidential – Prosecution Bar” information abides by the provisions of this Order;

e) Mock jurors and/or judges engaged by any consultant in preparation for trial, provided they acknowledge that they will abide by this Order by signing the attached Acknowledgement;

f) The Court and the Court’s staff;

g) No more than two (2) total in-house attorneys employed by a non-producing party provided the individual is designated in writing pursuant to the requirements of Paragraph 9 below;<sup>1</sup>

h) Any person to whom the designating party otherwise agrees in writing (for the avoidance of doubt, this Subparagraph does not serve to limit any other Subparagraph within Paragraph 7); and

i) Any person to the extent required by Court Order.

8. The persons identified in Paragraphs 7(c), 7(d), 7(e), and 7(g) above, and the contract or temporary attorneys identified in Paragraph 7(a) above, shall not be permitted access to “Highly Confidential – Attorneys’ Eyes Only” information unless and until they agree in writing to be bound by this Order by signing an Acknowledgement substantially in the form of Attachment A or Attachment B hereto. The persons identified in Paragraphs 7(c), 7(d), 7(e), and 7(g) above, and the contract or temporary attorneys identified in Paragraph 7(a) above, shall not be permitted access to “Highly Confidential – Prosecution Bar” information unless and until they

---

<sup>1</sup> Absent consent by the producing party, Plaintiff shall not disclose documents or information marked “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” produced by one defendant to any in-house attorneys of another defendant. Plaintiff agrees to notify each defendant that it is disclosing that defendant’s confidential information to another defendant’s expert or outside counsel. The notification shall be provided before or at the time the disclosure occurs.

agree in writing to be bound by this Order by signing an Acknowledgement substantially in the form of Attachment B hereto. Outside counsel of record shall retain copies of all executed Acknowledgements. Except as provided in Paragraph 9 below, copies need not be provided until the final termination of the above-captioned cases and at the written request of the producing party.

9. The procedure for the disclosure of any “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” information to the persons described in Paragraphs 7(d) and 7(g) shall be as follows:

a) The party seeking to disclose such information shall, at least ten (10) days before such disclosure, disclose to outside counsel for each producing party:

- i) The name of the person to whom the party seeks to disclose the information;
- ii) The present employer, responsibilities and title of the person;
- iii) A signed, written Acknowledgement (substantially in the form of Attachment A or B) by the person that he/she has read this Order, agrees to be bound by its terms, and consents to the jurisdiction of this Court for enforcement of this Stipulated Protective Order; and
- iv) For consultants or experts, a current resume or curriculum vitae, a list of all publications authored in the previous ten (10) years, a list of all cases in which he/she has testified at trial or deposition within the past four (4) years, and identification of any consulting or other relationship to the parties in this action within the last five years (excluding non-testifying litigation consulting, the existence of which is protected by attorney work product immunity).

b) Within ten (10) days after receipt of the information described in Paragraph 9(a), a party may object to the disclosure of information designated as “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” to the proposed recipient. Such objection must be made by serving a written objection on the party seeking to make the disclosure, and shall clearly set forth the basis (or bases) for the objection. Counsel shall endeavor in good faith to resolve the objection on an informal basis before presenting the matter to the Court for resolution. If the parties are unable to resolve the objection, the objecting party may move the Court for a protective order preventing the disclosure of information designated as “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” to the proposed recipient. Such motion must be filed and served within ten (10) days of service of the party’s written objection; otherwise, the objection is deemed waived. The objecting party shall have the burden of proof. Until the objection has been resolved by agreement of counsel, waiver, or order of the Court, no disclosure of “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” designated information shall be made to the proposed recipient.

10. Any person who receives “Highly Confidential – Prosecution Bar” information pursuant to Paragraph 7(a), 7(d), 7(g), or 7(h) shall not engage in any patent prosecution of patent applications relating to the formulation and/or use of tasimelteon formulations, including without limitation any patent application claiming priority to any of the patents asserted in this action, before any foreign or domestic agency, until one year after the conclusion of this action, including any appeals thereof. For clarity, this restriction does not include inter partes and post grant reviews provided that participation in the inter partes and post grant reviews does not

include preparing, assisting in, or otherwise participating in drafting or amending patent claim(s) related to the formulation and/or use of tasimelteon formulations.

11. In addition, any person who receives “Highly Confidential – Prosecution Bar” information pursuant to Paragraph 7(a), 7(d), 7(g), or 7(h) shall not participate in the preparation or submission of any FDA correspondence (including, but not limited to citizens petitions) or correspondence with the United States Pharmacopoeia, or any other similar foreign or domestic agency regarding approval requirements of tasimelteon formulations until one year after the conclusion of this action, including any appeals thereof. For clarity, this restriction does not include Plaintiff’s and Defendants’ work to obtain approval of, or amending, their respective NDA and ANDAs.

12. Any “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” material to be filed with the Court in connection with the above-captioned cases shall be filed under seal in accordance with the applicable procedures set forth in the Local Rules for the United States District Court for the District of Delaware and/or the applicable procedures established by the clerk of the Court. The parties consent to service of sealed filings via electronic means.

13. No receiving party shall be under any obligation to object to the designation of any document or information as “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” at the time such designation is made, or at any time thereafter, and no party shall, by failure to object, be found to have acquiesced or agreed to such designation or be barred from objecting to such designation at any time. If the receiving party at any time objects to the designation of any information as “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar,” such party shall state the objection in writing

to counsel for the designating party. Counsel shall endeavor in good faith to resolve the objection on an informal basis before presenting the matter to the Court for resolution. If the parties are unable to resolve the objection, the objecting party may move the Court for an order changing or removing the designation. On such a motion, the producing party who has made a claim that a document qualifies as “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” shall have the burden of proving that the material it designated as “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” information contains or discloses the party’s confidential and proprietary business information, processes, operations, research, technical or developmental information, production, marketing, sales, shipments or other proprietary data or confidential information of commercial value, including, but not limited to, trade secrets, or is subject to confidentiality obligations to third parties. Until an objection to the designation of a document has been resolved by agreement of counsel or by order of the Court, the document shall be treated as designated and subject to the terms of this Order.

14. No party shall be responsible to another for any use made of information produced or disclosed hereunder and not identified or designated as “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar.” However, the inadvertent or unintentional disclosure by the producing party of confidential information without designating the same shall not be deemed a waiver in whole or in part of such party’s claim of confidentiality, and such designation may be made after the discovery of the inadvertent production or disclosure by identifying to the receiving party in writing the “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” information and the confidential nature of the information. Thereafter, such confidential information shall be

considered as having been designated as “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” and shall be deemed to be subject to the terms of this Order. The parties shall cooperate to make reasonable efforts to cure any inadvertent or unintentional disclosure of information designated as “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” pursuant to this Paragraph. Any Producing Party may change or add a designation of “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” (or withdraw a designation) regarding any material that it has produced in any way, irrespective of care or fault, by notifying counsel for each party in writing. Upon receipt of such notice, the non-producing Party shall: (i) not make any further disclosure or communication of such newly designated material except as provided for in this Order; (ii) take reasonable steps to notify any persons known to have possession of any material with the original designation (or lack of designation) and alert those persons of the effect of such a change in designation under this Order; and (iii) for material newly designated as “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar,” promptly retrieve or have destroyed all copies and transcriptions of such originally designated (or undesignated) material from any persons known to have possession of such material who are not specified in Paragraph 7. Properly marked documents, reflecting the new designation, shall be promptly provided by the producing party.

15. Should any document or information designated as “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” hereunder be disclosed through inadvertence to any person or party not entitled to receive the same hereunder, then the parties intend to have such person be automatically bound by this Order with respect to the “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar”

document or information disclosed, and such person shall be informed promptly of the provisions of this Order by the receiving party and shall sign an Acknowledgement in accordance with Paragraph 8 above. The parties shall exercise all reasonable efforts to retrieve any such information disclosed to persons not authorized to receive the information under this Order.

16. The inadvertent production or disclosure of any document or thing, produced in any way, irrespective of care of fault, otherwise protected by the attorney-client privilege, work-product immunity, or any other applicable privilege or immunity, or information that is irrelevant to this proceeding or otherwise not discoverable, or information inadvertently produced by a third party (*e.g.*, a third-party vendor) shall not operate as a waiver of any such privilege or immunity if, after learning that the inadvertent production or disclosure was made, the party who made the inadvertent production or disclosure sends to each receiving party a written request for return of the inadvertently produced or disclosed document or thing. Any request for the return or destruction of inadvertently produced documents or things must be made within twenty (20) days after: (1) the privileged information is used in a deposition attended by the producing party, cited in or attached to a court filing in this case, discovery response served on the producing party, or written correspondence received or sent by the producing party; or (2) the producing party otherwise discovers that the information has been produced or disclosed. The request must specify the privilege or immunity claimed. Subject to the provisions of this Paragraph, within five (5) business days of receiving such a request, the receiving party shall either return to the producing party the original and all copies of such documents and things identified by the producing party as being privileged or work-product and as having been inadvertently produced, or represent in writing that all such documents and materials have been destroyed.

a) Within ten (10) business days after receiving the documents or confirmation of their destruction from the receiving party, the producing party shall provide to the receiving party a list identifying all such inadvertently produced documents and things and providing details sufficient to allow the receiving party to assess the privilege claim. To the extent that only a portion of a returned document or thing contains information that is protected by the attorney-client privilege or by work-product immunity, the producing party shall also provide to the receiving party replacements for the returned documents or things with the protected information redacted from such documents or things.

b) Within five (5) days after receiving the list described in subparagraph a), the receiving party shall notify the producing party in writing if it disputes that any such document or thing was inadvertently produced or is protected by the attorney-client privilege, work-product immunity, or any other applicable privilege or immunity.

c) Counsel shall endeavor in good faith to resolve any disputes over any claimed privileges or immunities before presenting the matter to the Court for resolution. If the parties are unable to resolve the disputes, within fifteen (15) business days after receiving the basis for the claim of privilege or immunity the receiving party shall move the Court to compel the production of the returned documents. The receiving party shall not use the substantive content of the inadvertently produced document or thing to challenge its status as privileged or immune, but may require the producing party to submit the document or thing under seal for *in camera* review. If the receiving party does not move the Court within fifteen (15) business days, the receiving party waives the opportunity to challenge the claim of privilege for that document. The parties agree that



any motions to compel and the related briefs will be filed under seal. The producing party shall have the burden of proving that the documents in dispute are protected by the applicable privilege or immunity.

d) The disposition of documents containing information derived from such inadvertently produced documents shall be addressed on a case-by-case basis by agreement of counsel or by order of the Court.

e) In the event that the receiving party discovers material it knows or reasonably should know to be inadvertently or unintentionally produced or disclosed that is protected by the attorney-client privilege or work-product immunity before it has been notified by the producing party, the receiving party must promptly notify, in writing, the producing party of the suspected inadvertent or unintentional disclosure.

17. Notwithstanding this Order, a party may disclose:

a) its own “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” material to non-parties as it sees fit;

b) another party’s “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” material:

i) to any person who authored, received, or previously had access to or knowledge of the information as clearly and objectively demonstrated by the information itself or as clearly and objectively established by other documents or testimony;

ii) to any officer, director, employee, attorney, corporate deponent, consultant, or agent of that other party, or to any former officer, former director, former employee, former attorney, former consultant, or former agent of that

other party, provided that the document or thing, or testimony given in this case, objectively and clearly establishes that the former officer, former director, former employee, former attorney, former consultant, or former agent had received it or had access to it.

iii) to any expert retained by any party subject to Paragraph 7(d) in the above-captioned cases;

iv) to the any party's outside counsel representing that party in the above-captioned actions; or

v) if the producing party or outside counsel to the producing party permits such disclosure;

c) a nonparty's "Highly Confidential – Attorneys' Eyes Only" or "Highly Confidential – Prosecution Bar" material as produced by that nonparty:

i) to any person who authored, received, or previously had access to or knowledge of the information as objectively and clearly demonstrated by the information itself or as objectively and clearly established by other documents or testimony;

ii) to any officer, director, employee, attorney, corporate deponent, consultant, or agent of that nonparty, or to any former officer, former director, former employee, former attorney, former consultant, or former agent of that nonparty, provided that the document or thing, or testimony given in this case, objectively and clearly establishes that the nonparty former officer, former director, former employee, former attorney, former consultant, or former agent had received it or had access to it; or

iii) if the nonparty or outside counsel to the nonparty party permits such disclosure.

18. The confidentiality obligations of this Order shall not apply or shall cease to apply to any information that, upon agreement by the parties, by order of the Court, or upon good cause shown:

a) at the time of disclosure hereunder, was already in the public domain by publication or otherwise;

b) since the time of disclosure hereunder, has become, through no act or failure on the part of the receiving party, part of the public domain by publication;

c) at the time of disclosure hereunder, was already lawfully in the possession of the receiving party and was not acquired directly or indirectly from the producing party or from any nonparty or party under obligation of confidence to the producing party;

d) after disclosure hereunder, was acquired by the receiving party from a nonparty lawfully possessing the same and having no obligation to the producing party hereunder;

e) the producing party agrees may be disclosed to a nonparty under no obligation of confidentiality; or after disclosure hereunder, was developed by the receiving party independently of any “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” information from the producing party.

19. Nothing in this Order shall be construed to require production of “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” information deemed by counsel possessing such information to be privileged or otherwise protected from

discovery. The entry of this Order shall not constitute a waiver by the parties of any objections to disclosure and/or production of any information during discovery.

20. If discovery in the above-captioned cases calls for the production of information the disclosure of which would breach an express or implied agreement by that party with a nonparty to maintain such information in confidence, the party requested to produce the information shall first give written notice to the nonparty with a copy of this Order. When such written notice is given to the nonparty, the party requested to produce the information will advise the other parties to the above-captioned cases that such notice has been given.<sup>2</sup> If the nonparty consents to the production, the requested information shall be produced in accordance with this Order. If the nonparty objects to the production of such information, the party requested to produce shall not produce the information without an order from the Court directing it to do so. If a party seeks discovery from a nonparty, either the nonparty or the parties may invoke the terms of this Order with respect to any confidential information provided by the nonparty to the parties by so advising all parties to the above-captioned cases in writing. Any such nonparty shall have standing to appear in the above-captioned cases to file motions and oppose motions, as necessary, to protect such nonparty's rights in its confidential information.

21. If, in responding to a discovery request, subpoena, other legal process or otherwise, a nonparty discloses "Highly Confidential – Attorneys' Eyes Only" or "Highly Confidential – Prosecution Bar" information belonging to or owned by a party, and the nonparty otherwise has an obligation to keep the information confidential, the information disclosed by the nonparty shall be accorded the same protection as if it were received from a producing party

---

<sup>2</sup> If the party requested to produce the information is one of the Defendants, the Defendant need only advise the Plaintiff (not the other Defendants) that it has given written notice to the nonparty.

under this Order. In such an event, a party, in good faith believing the information disclosed to be its “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” information, may designate such information pursuant to this Order. Likewise, a nonparty disclosing its own or a party’s “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” information may do so under the terms of this Order if the nonparty first agrees in writing to the terms of this Order, and, thereafter, the information disclosed by the nonparty shall be accorded the same protection as if it were received from a producing party under this Order. Any party subject to this Order may object to the designation of information received from nonparties under the provisions contained in Paragraph 13 of this Order.

22. The parties agree to exclude from discovery all draft expert reports and, unless containing facts or evidence relied on in forming the expert’s opinions in this case, all communications between the parties’ attorneys and any witness required to provide a report under Rule 26(a)(2)(B), and/or any staff, support personnel, contract laboratory, or agent of such witness, and any draft expert reports and communications regarding the same between the parties’ experts and their staff, agents, support personnel, or contract laboratory, regardless of the form of the communications. The parties and their testifying experts must otherwise comply with the disclosure requirements set forth in Federal Rule of Civil Procedure 26(a)(2).

23. In the event that a new party is added, substituted or brought into the case, or in the event that new or substitute counsel is retained by a party, this Order shall be binding on and inure to the benefit of the new party, subject to the right of the new party to seek relief from or modification of the Order.

24. Except as set forth in this Paragraph, within ninety (90) days following final termination of this litigation, including any appeals, the originals of all produced documents or things designated “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” and all reasonably accessible copies thereof (including those provided to outside experts and other third parties), but excluding those provided to the Court, shall be returned to the producing party or destroyed. Notwithstanding the foregoing, no party is obligated to return or destroy information designated as “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” that is contained on electronic backup or archival media. Notwithstanding the foregoing and subject to a continuing obligation to protect all such material pursuant of this Protective Order, neither the parties nor the Court shall be obliged to return or destroy any production documents or production things (or any photocopies thereof) that were admitted into evidence at trial or any hearing; incorporated (as an exhibit, appendix, or otherwise) as part of a document filed with or submitted to the Court; incorporated (as an exhibit, appendix, or otherwise) as part of an expert report. Further, outside counsel may retain archive copies of filings, court papers, correspondence, deposition and trial transcripts, deposition and trial exhibits, expert reports, written discovery responses, and attorney work product (regardless of whether such materials contain or reference information designated “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar”).

25. The terms of this Order shall survive the final termination of the above-captioned cases to the extent that any “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar” information is not or does not become known to the public.

26. This Order shall be binding upon the parties hereto, upon their attorneys, and upon the parties’ and their attorneys’ successors, executors, personal representatives,

administrators, heirs, legal representatives, assigns, subsidiaries, divisions, officers, directors, employees, agents, and independent contractors, and other persons or organizations over which they have control.

27. Nothing in this Order shall bar or otherwise restrict any attorney herein from rendering advice to the attorney's party-client with respect to the above-captioned cases, and in the course thereof, relying upon an examination of "Highly Confidential – Attorneys' Eyes Only" or "Highly Confidential – Prosecution Bar" information; provided, however, that in rendering such advice and in otherwise communicating with the party client, the attorney shall not disclose any "Highly Confidential – Attorneys' Eyes Only" or "Highly Confidential – Prosecution Bar" information nor the source of any "Highly Confidential – Attorneys' Eyes Only" or "Highly Confidential – Prosecution Bar" information to anyone not authorized to receive such information pursuant to the terms of this Order.

28. Any party may retrieve and refile under seal any document containing "Highly Confidential – Attorneys' Eyes Only" or "Highly Confidential – Prosecution Bar" information that was filed with the Court prior to entry of this Order.

29. This Order may be changed by further order of the Court, and is without prejudice to the rights of any party to move for relief from any of its provisions, or to seek or agree to different or additional protection for any particular material or information.

30. Until such time as this Order has been entered by the Court, the parties agree that, upon execution by the parties, it will be treated as though it had been "So Ordered."

31. The Court retains jurisdiction even after the termination of the case to enforce this Order and to make such amendments, modifications, deletions and additions to this Order as the Court may deem appropriate.

32. Other Proceedings. By entering this order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a motion to disclose another party's information designated as confidential pursuant to this order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

**SO ORDERED** this \_\_\_\_ day of \_\_\_\_\_, 2018

---

United States District Judge



IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

VANDA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 18-651 (CFC) (CJB)
	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Defendant.	)	
<hr/>		
VANDA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 18-689 (CFC) (CJB)
	)	
APOTEX INC. and APOTEX CORP.,	)	
	)	
Defendants.	)	
<hr/>		
VANDA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 18-690 (CFC) (CJB)
	)	
MSN PHARMACEUTICALS INC. AND	)	
MSN LABORATORIES PRIVATE	)	
LIMITED,	)	
	)	
Defendants.	)	
<hr/>		

**ATTACHMENT A**

**Acknowledgement To Be Bound By Stipulated Protective Order**

I, \_\_\_\_\_, certify that:

(a) My present residential address is

\_\_\_\_\_.

(b) My present employer is \_\_\_\_\_  
and the address of my present employer is \_\_\_\_\_.

(c) My present occupation or job description is \_\_\_\_\_.

I have read a copy of the Stipulated Protective Order entered in this case. During my participation in this case, I may read or hear information designated “Highly Confidential – Attorneys’ Eyes Only.” I consent to be subject to the jurisdiction of the Court for enforcement of this Stipulated Protective Order.

I agree not to disclose such confidential information to any person not entitled to receive disclosure of such confidential information under the Order; not to use such confidential information for purposes beyond my participation in this case; and to abide by the Order in every respect.

Upon conclusion of the above-captioned litigation, including any appeal, I will use my best efforts to destroy or return to outside counsel all Highly Confidential – Attorneys’ Eyes Only information that I received that are in my possession.

Signed: \_\_\_\_\_

Dated: \_\_\_\_\_

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

VANDA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 18-651 (CFC) (CJB)
	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Defendant.	)	

VANDA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 18-689 (CFC) (CJB)
	)	
APOTEX INC. and APOTEX CORP.,	)	
	)	
Defendants.	)	

VANDA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 18-690 (CFC) (CJB)
	)	
MSN PHARMACEUTICALS INC. AND	)	
MSN LABORATORIES PRIVATE	)	
LIMITED,	)	
	)	
Defendants.	)	

**ATTACHMENT B**

**Acknowledgement To Be Bound By Stipulated Protective Order**

I, \_\_\_\_\_, certify that:

(a) My present residential address is

\_\_\_\_\_.

(b) My present employer is \_\_\_\_\_  
and the address of my present employer is \_\_\_\_\_.

(c) My present occupation or job description is \_\_\_\_\_.

I have read a copy of the Stipulated Protective Order entered in this case. During my participation in this case, I may read or hear information designated “Highly Confidential – Attorneys’ Eyes Only” or “Highly Confidential – Prosecution Bar.” I consent to be subject to the jurisdiction of the Court for enforcement of this Stipulated Protective Order.

I agree not to disclose such confidential information to any person not entitled to receive disclosure of such confidential information under the Order; not to use such confidential information for purposes beyond my participation in this case; and to abide by the Order in every respect.

Upon conclusion of the above-captioned litigation, including any appeal, I will use my best efforts to destroy or return to outside counsel all Highly Confidential – Attorneys’ Eyes Only or Highly Confidential – Prosecution Bar information that I received that are in my possession.

Signed: \_\_\_\_\_

Dated: \_\_\_\_\_